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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,975	09/15/2003	Mitchell P. Fink	3403.1001-007	2253
21005	7590	12/15/2004	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.			HENLEY III, RAYMOND J	
530 VIRGINIA ROAD			ART UNIT	
P.O. BOX 9133			PAPER NUMBER	
CONCORD, MA 01742-9133			1614	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/662,975	FINK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Raymond J Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on November 3, 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,5,6,8-11,13,15-17,19 and 24-31 is/are rejected.
- 7) Claim(s) 3,4,7,12,14,18,20,22 and 23 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**CLAIMS 1-31 ARE PRESENTED FOR EXAMINATION**

Applicants' Amendment and the declaration under 37 C.F.R. § 1.132 of Dr. Fink filed November 3, 2004 have been received and entered into the application. Accordingly, the specification at page 4 and claims 1, 12, 16, 21, 22, 24, 25 and 28-31 have been amended.

In view of such amendments, as well as Applicants' remarks at page at pages 8 and 9 of the amendment, the objection to claim 12, rejection of claims 1-31 under 35 U.S.C. § 112, first paragraph and rejection of claims 1, 2, 4 and 5 under 35 U.S.C. § 102(e), as set forth in the previous Office action dated July 1, 2004, are each withdrawn.

***Claim Objection***

Claims 3, 4, 7, 12, 14, 18, 20, 22 and 23 are objected to as depending from a rejected base claim, but are otherwise in condition for allowance. These claims are either directed to ethyl pyruvate, e.g., claim 4, or to alpha-ketoalkanoic acids that are not taught or suggested by the references of record, e.g., claim 3. See below for the Examiner's reasons for finding that claims directed to ethyl pyruvate are allowable.

***Claim Rejection - 35 USC § 103***

Claims 1, 2, 5, 6, 8-11, 13, 15-17, 19, 21 and 24-31 are rejected under 35 U.S.C. 103(a) as being obvious over Katz (U.S. Patent No. 5,798,388) in view of Ajami et al. (U.S. Patent Application Publication No. 2003/0073743), each of record, for the reasons of record as set forth in the previous Office action dated July 1, 2004 at pages 3-7, as applied to claims 1, 2, 4-13, 15-17 and 19-31.

Applicants' arguments at pages 9-12 of their amendment and the declaration under 37 C.F.R. § 1.132 of Dr. Fink have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

***Administration of Ethyl Pyruvate for the Claimed Purposes Would Not Have Been Obvious***

Initially, the Examiner acknowledges that the declaration of Dr. Fink establishes that ethyl pyruvate provides for far superior protection against LPS-induced gut barrier dysfunction and inhibition of elevated levels of expression of ICAM-1 in cells stimulated by IL-1 $\beta$ , as compared to sodium pyruvate. Such protection is representative of the scope of the claims with regard to the therapeutic objective of treating a cytokine-mediated inflammatory condition (see Dr. Fink's remarks at page 3, paragraph 5 of the declaration). Also, such results represent a comparison between the claimed invention, to the extent that the claims encompass ethyl pyruvate, and the closest art, i.e., the Katz patent, which exemplifies the use of pyruvate salts for the treatment of inflammatory conditions. Accordingly, Applicants have overcome the Examiner's presumption that it would have been obvious to employ ethyl pyruvate for the purposes claimed. Therefore, the claims directed to ethyl pyruvate, e.g., claim 4, are no longer subject to the present rejection.

***Conclusion of Obviousness is Proper***

At pages 9-10 of their amendment, Applicants have argued that one of ordinary skill in the art would not have been motivated to use pyruvate esters, such as those disclosed by Ajami et al., in the method taught by Katz. In support of their position, Applicants have urged that only pyruvic acid itself, pyruvic acid salts or amides of pyruvic acid are taught by Katz and thus the skilled artisan would have had no motivation to employ the pyruvic acid esters of Ajami et al. in

the method taught by Katz. The Examiner cannot agree with applicants' position. The Examiner acknowledges that Katz discloses pyruvic acid itself, pyruvic acid salts and amides of pyruvic acid. However, the broad teaching of Katz that "the preferred inflammatory mediator is at least one compound selected from the group consisting of *a pyruvate precursor, pyruvate, a lactate precursor and lactate*. A precursor is a substance from which another substance is formed in this text also includes salts." (col. 7, lines 21-25) adequately provides a basis for concluding that a pyruvate ester would have been obvious. This is because the general terms "a pyruvate precursor" and "pyruvate" are indicative of a genus of pyruvate compounds of which esters would be apart. While Katz exemplifies only salts and amides, it is clear from the broad teachings quoted above that the patentee does not limit his invention to the use of only pyruvic acid itself, pyruvate salts or pyruvate amides. "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971)." (MPEP 2123, under the heading "NONPREFERRED EMBODIMENTS CONSTI-TUTE PRIOR ART").

***The Showing of Unobviousness is Not Commensurate in Scope with the Claims***

Applicants have also argued that the present invention is non-obvious over the combined teachings of Katz and Ajami et al. because unexpected properties have been demonstrated. As noted above, the Examiner acknowledges that unexpected results have been demonstrated in the declaration of Dr. Fink. These results, however, do not provide a basis for concluding that the claimed subject matter would not have been obvious because the results are limited to only a single ester, i.e., ethyl pyruvate, while the claims subject to this rejection encompass pyruvic acid esters as a group. Further, it has not been argued or demonstrated on the record that the results

obtained with ethyl pyruvate would be exemplary of results that would occur with all of the pyruvate esters encompassed by the claims.

In this regard, the Examiner cites MPEP 2144.08(II)(B) which reads in-part:

“When considering whether proffered evidence is commensurate in scope with the claimed invention, Office personnel should not require the applicant to show unexpected results over the entire range of properties possessed by a chemical compound or composition.

See, e.g., *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987).

Evidence that the compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a prima facie case of obviousness. *Id.*

For example, a showing of unexpected results for a single member of a claimed subgenus, or a narrow portion of a claimed range would be sufficient to rebut a prima facie case of obviousness *if* a skilled artisan ‘could ascertain a trend in the exemplified data that would allow him to reasonably extend the probative value thereof.’ *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Evidence of the unobviousness of a broad range can be proven by a narrower range when one skilled in the art could ascertain a trend that would allow him to reasonably extend the probative value thereof.). But see, *In re Grasselli*, 713 F.2d at 743, 218 USPQ at 778 (evidence of superior properties for sodium containing composition insufficient to establish the non-obviousness of broad claims for a catalyst with ‘an alkali metal’ where it was well known in the catalyst art that different alkali metals were not interchangeable and applicant had shown unexpected results only for sodium containing materials); *In re Greenfield*, 571

F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978) (evidence of superior properties in one species insufficient to establish the nonobviousness of a subgenus containing hundreds of compounds); *In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972) (one test not sufficient where there was no adequate basis for concluding the other claimed compounds would behave the same way).” (emphasis added)

Here, a single pyruvic acid ester has been tested and shown to possess unexpected properties. However, just as a single point in space fails to define a line, the results demonstrated for ethyl pyruvate are not deemed sufficient to establish non-obviousness of the presently claimed genus of pyruvate esters.

For the above reasons, the claims are deemed properly rejected.

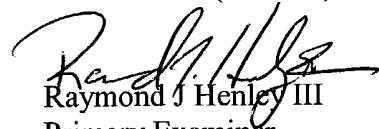
**THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Raymond J. Henley III  
Primary Examiner  
Art Unit 1614

December 12, 2004